

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF MICHIGAN  
SOUTHERN DIVISION

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TRUTEK CORP.,  
Plaintiff,

v.

BlueWillow Biologics, Inc.  
ROBIN ROE 1 through 10, gender  
neutral fictitious names, and ABC  
CORPORATION 1 through 10  
(fictitious names).

Defendants.

CIVIL ACTION No. 2:21-cv-10312-SJM-RSW

Hon. Stephen J. Murphy, III

**PLAINTIFF'S BRIEF IN REBUTTAL TO DEFENDANT'S  
OPPOSITION TO PLAINTIFF'S MOTION FOR LEAVE  
TO AMEND COMPLAINT**

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In its Opposition to Trutek's Motion For Leave to Amend, Defendant characterized this matter as "a classic nuisance patent lawsuit." However, defending a patent is not a nuisance. Patents that are not defended against any infringer become void against all infringers. Plaintiff intends to vigorously defend its patents. In addition, Defendant characterized Plaintiff's legitimate inquiries into possible infringement as a "fishing expedition." That term is used when a party seeks to discover information unrelated to a lawsuit. That is not the case here.

### **LEGAL STANDARD**

As previously set forth in Plaintiff's Brief supporting its Motion for Leave to File an Amended Complaint, Fed. R. Civ. P. 15(a)(2) provides that courts should "freely give leave" to the moving party to amend the complaint "when justice so requires." In deciding whether to grant such relief, courts must consider "the delay in filing, the lack of notice to the opposing party, bad faith by the moving party, repeated failure to cure deficiencies by previous amendments, undue prejudice to the opposing party, and futility of amendment." *Perkins v. American Elec. Power Fuel Supply, Inc.*, 246 F.3d 593, 605 (6th Cir. 2001). Plaintiff has met its burden under this standard.

## **ARGUMENT**

**1. ANY DELAY BY PLAINTIFF IN FILING ITS MOTION IS JUSTIFIED BY DEFENDANT'S FAILURE TO COOPERATE WITH PLAINTIFF'S ATTEMPTS AT DISCOVERY.**

This action was filed on February 10, 2021 alleging a single count of infringement of Plaintiff's U.S. Patent No. 8,163,802 (the '802 Patent) by Defendant BlueWillow Biologics, Inc. ("BlueWillow"). BlueWillow manufactured and marketed an infringing product, Nanobio® Protect. At the time the original action was filed, Plaintiff, Trutek Corp. ("Trutek") was unaware that BlueWillow was also developing vaccines to evoke an immune response to various illnesses and maladies. BlueWillow's website indicated that its Nanobio® Protect product utilized Bluewillow's patented technology. Yet, no patents were listed on the product's packaging. At the time this action was filed, there were no patents assigned to BlueWillow. Over a period of time, Trutek discovered patents for nanoemulsion vaccines filed by inventors associated with BlueWillow. Those patents were assigned to the University of Michigan or to Nanobio Corporation.<sup>1</sup> The Court was informed of Trutek's intention to seek discovery concerning BlueWillow's vaccines at the Scheduling Conference held on November 3, 2021. BlueWillow's counsel stated firmly that it would resist all efforts by Trutek

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<sup>1</sup> At some point, Nanobio Corporation, a Michigan corporation, changed its corporate name to BlueWillow, and reincorporated in Delaware.

to discover anything about its vaccines. Instead, they denied infringement and stated that their vaccines had blanket protection of the Hatch Waxman safe harbor of 35 U.S.C. § 271(e)(1). Meantime, Trutek had consulted with experts who told them that the nanoemulsion vaccines disclosed in the vaccine patents and on BlueWillow's website necessarily infringed on claims of the '802 Patent.

Trutek served requests for admission and interrogatories on BlueWillow. All of BlueWillow's responses to discovery addressing its vaccines alleged safe harbor protection, and were objected to as constituting a "fishing expedition" and not at issue in this lawsuit.

Owing to BlueWillow's staunch resistance to discovery regarding its vaccines and Trutek's good faith belief that these products read upon the '802 Patent's claims, Trutek has no alternative but to submit a complaint that would cause these products to be at issue in this lawsuit.

**2. TRUTEK PROVIDED AMPLE NOTICE TO BLUEWILLOW THAT ITS VACCINES ARE AT ISSUE.**

As early as April 2021, Trutek informed BlueWillow that its vaccines potentially infringe the '802 Patent. At the Rule 16 Scheduling Conference held in November 2021, Trutek made it very clear that BlueWillow's vaccines are at issue in this lawsuit. This was reinforced by Trutek's requests for admission and interrogatories. BlueWillow cannot now deny

knowledge of Trutek's intentions to bring its vaccines into this lawsuit and to conduct discovery thereof.

**3. TRUTEK'S REQUEST FOR PERMISSION TO AMEND ITS COMPLAINT WAS MADE BASED ON A GOOD FAITH BELIEF THAT BLUEWILLOW'S VACCINES INFRINGE THE '802 PATENT.**

Because BlueWillow's Nanobio<sup>®</sup> Protect product was commercially available, Trutek was able to experimentally confirm its belief that this product infringed claims of its '802 Patent. This was not the case for BlueWillow's vaccines. Patent applications and scientific papers submitted by scientists associated with BlueWillow confirm the very nature of their vaccine development effort. BlueWillow's website confirms that their developmental vaccines utilize this technology.

Lacking experimental evidence of infringement, Trutek turned to outside experts for assistance. These experts researched extensively published scientific information related to BlueWillow's vaccines. Based on their opinions, Trutek developed a good faith belief that the vaccines infringe the '802 Patent.

Although BlueWillow repeatedly made vague assertions that their vaccines were protected by the Hatch Waxman safe harbor, they refused to provide any information to test those assertions. There are several exceptions to the safe harbor. Trutek was not given the opportunity to test

whether all of BlueWillow's activities were solely "for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products," as required by the statute.

Whether the safe harbor applies to the vaccines is an affirmative defense requiring proof by BlueWillow. "Plaintiff is entitled to discovery to test the allegations of the defendant regarding the defense." *Ventrassist Pty Ltd. v. Heartware, Inc.*, 377 F. Supp. 2d 1278, 1286-88 (S.D. Fla. 2005). Here, the district court held that plaintiffs were not required to negate the safe harbor affirmative defense in its complaint.

In addition, Trutek seeks information regarding other business entities cooperating with BlueWillow in its vaccine program that may also be infringing the '802 Patent.

**4. AMENDING THE COMPLAINT TO ENCOMPASS BLUEWILLOW'S VACCINES WOULD NOT CAUSE UNDUE PREJUDICE BECAUSE IT HAD AMPLE NOTICE OF TRUTEK'S INTENTIONS.**

The only additional allegation made by Trutek in its proposed amended complaint is a single new count of infringement of the '802 Patent by BlueWillow's vaccines. BlueWillow was aware of Trutek's allegations as early as mid-2021. BlueWillow understood that its vaccines are fair game for inquiry in this lawsuit. BlueWillow should not be allowed to resist

discovery into its previously known allegations of infringing activity and then benefit by that resistance. Granting Trutek's motion will not create undue prejudice against BlueWillow.

**5. TRUTEK'S AMENDMENT OF ITS COMPLAINT IS NOT FUTILE BECAUSE ITS PROPOSED COMPLAINT IS WELL-PLED AND SHOULD SURVIVE A MOTION TO DISMISS.**

"A proposed amendment is futile if the amendment could not withstand a Rule 12(b)(6) motion to dismiss." *Rose v. Hartford Underwriters Ins. Co.*, 203 F.3d 417, 420 (6th Cir. 2000) (citing *Thiokol Corp. v. Dep't of Treasury, State of Michigan, Revenue Div.*, 987 F.2d 376, 382 (6th Cir. 1993)). In order to survive a Rule 12(b)(6) motion to dismiss, a complaint must allege "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). A plaintiff must allege "specific factual allegations to support each claim"; "a formulaic recitation of the elements of a cause of action will not suffice." *Twombly*, 550 U.S. at 555 (internal quotations omitted).

Paragraphs 6-13 and 45-46 of Trutek's proposed amended complaint (ECF 28-4) put forth a generic set of supporting facts. Paragraphs 7-24 put forth specific facts supporting Trutek's allegations of infringement by

BlueWillow's Nanobio® Protect product. Paragraphs 25-44 put forth specific facts supporting Trutek's allegations of infringement by BlueWillow's vaccines. Trutek's proposed amended complaint complies with the *Twombly/Iqbal* standard. The facts set forth in these paragraphs are sufficient to fairly place BlueWillow on notice of Trutek's allegations of patent infringement, and if shown to be true, tend to establish BlueWillow's liability.

**6. ATTEMPTS TO SETTLE THIS MATTER THROUGH  
MEDIATION WILL NOT SUCCEED UNLESS VACCINES ARE  
CONSIDERED.**

At BlueWillow's request, the mediation session scheduled for June 14th will be postponed until late June or sometime in July. In setting the original June date, court-appointed mediator, Thomas Schehr, understood that there is a dispute over the issues in this case, and that without adequate discovery, arriving at a settlement would be difficult.

**CONCLUSION**

In light of the rebuttal arguments presented *supra*, Plaintiff's Motion for Leave to Amend its Complaint should be granted.

Dated: May 31, 2022

Respectfully,

s/ Stanley H. Kremen  
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**CERTIFICATE OF SERVICE**

I certify that on May 31, 2022, I served the foregoing Plaintiff's Plaintiff's Brief in Rebuttal to Defendant's Opposition to Plaintiff's Motion for Leave to Amend Complaint upon all parties herein by filing copies of same using the ECF System.



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